October 21, 2022

NuVasive, Incorporated
Jessica LeBlanc
Manager Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K221751
Trade/Device Name: NuVasive® Cohere® ALIF System Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: September 26, 2022
Received: September 29, 2022

Dear Ms. LeBlanc:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221751

Device Name
NuVasive Cohere ALIF System Intervertebral Body Fusion Device

Indications for Use *(Describe)*
The NuVasive Cohere ALIF System Intervertebral Body Fusion Device is indicated for spinal fusion procedures in skeletally mature patients. The Cohere ALIF System Intervertebral Body Fusion Device 10°-20° lordotic cages may be used as a standalone system. The Cohere ALIF System Intervertebral Body Fusion Device 25°-30° lordotic cages must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine. The System is designed for use with autogenous bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Cohere ALIF System Intervertebral Body Fusion Device is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Cohere ALIF System Intervertebral Body Fusion Device implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis or spinal stenosis at one or two adjacent levels, the Cohere ALIF System Intervertebral Body Fusion Device must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Jessica LeBlanc
Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
(951) 816-0973

Date Prepared: June 3, 2022

B. Device Name

Trade or Proprietary Name:	*NuVasive® Cohere® ALIF System Intervertebral Body Fusion Device*
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device
Device Class:	Class II
Classification:	21 CFR 888.3080
Product Code:	OVD

C. Predicate Devices

The subject *NuVasive Cohere ALIF System Intervertebral Body Fusion Device* is substantially equivalent to the primary predicate device *NuVasive Thoracolumbar Interbody Systems* (K23704) and the additional predicate devices, *NuVasive Thoracolumbar Interbody Systems* (K203201), and *NuVasive Foundation-LL System* (K152943).

D. Device Description

The *Cohere ALIF System Intervertebral Body Fusion Device* is inclusive of sterile, single use interbody implant grade polyetheretherketone (PEEK) devices, available in varied footprints and heights. Each device within the *Cohere ALIF System Intervertebral Body Fusion Devce* is comprised of a continuous body of PEEK formed into the final product shape with a porous architecture on select faces of the implant. In addition to PEEK, the device assembly contains radiolucent markets to enable visibility under x-ray in vivo. The implants are available in a variety of sizes and lordotic angles to suit the individual pathology and anatomical conditions of the patient. The *Cohere ALIF System Intervertebral Body Fusion Device* 10°-20° lordotic cages may be used as a standalone system. The *Cohere ALIF System Intervertebral Body Fusion Device* 25°-30° lordotic cages must be used with supplemental internal spinal fixation systems (e.g. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

E. Indications for Use

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F. Technological Characteristics

As was established in this submission, the subject *Cohere ALIF System Intervertebral Body Fusion Device* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject devices were shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function. This device does not contain software or electrical equipment.

G. Performance Data

Non-clinical testing was performed to demonstrate that the subject *Cohere ALIF System Intervertebral Body Fusion Device* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and Dynamic Compression (per ASTM F2077)
- Static and Dynamic Compression Shear (per ASTM F2077)
- Gravimetric and Particulate Analysis (ASTM F1714 and F1877)
- Subsidence and screw push-out analysis

The results demonstrate that the subject *Cohere ALIF System Intervertebral Body Fusion Device* meets the same criteria as the predicate devices, and the subject device was therefore found to be substantially equivalent to the predicates. No clinical studies were conducted.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *Cohere ALIF System Intervertebral Body Fusion Device* has been shown to be substantially equivalent to legally marketed predicate devices.